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| BENZION, G | |
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**DATE MAILED:** 06/28/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 5/02/94 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire three (3) month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. (2 pg)
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-67 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-67 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-67 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

**EXAMINER'S ACTION**

PTOL-326 (Rev. 2/93)

08/113561

This application should be examined for errors. For example at page 124 reference is made to US Patent Application number 07/204,388. This application matured into US Patent No. 5,258,300 on 11/02/93. Correction of this and all similar errors is required.

Applicants' attention is directed to Forms PTO-948 and 1474, regarding objections to the submitted drawings and necessary corrections.

The attempt to incorporate subject matter into this application by reference to 06/877,033 at page 12 of the specification is improper because the development of embryogenic maize calli and suspension culture for the purpose of devising cells for transformation is essential for the development and use of the claimed products -- transgenic maize plant -- and as such is considered essential. Incorporation by reference to any material deemed essential to other than a US Patent or an allowed application is improper. See MPEP 608.01(p).

The incorporation of essential material by reference to a foreign application or foreign patent or to a publication inserted in the specification is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or applicant's attorney or agent, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. In re Hawkins, 486 F.2d 569, 179 USPQ 157; In re Hawkins, 486 F.2d 579, 179 USPQ 163; In re Hawkins, 486 F.2d 577, 179 USPQ 167.

The use of the trademark IGNITE® at page 50, ROUNDUP® at page 109, and DuPont BIOLISTICS PDS 1000HE® at page 139 have been noted in this application. All trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title."

Claims 2-4 are rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-patentable subject matter..

The invention is directed to cells, progeny and seed derived from fertile transgenic maize plant. Although the claims from which these product depend has the limitation of "whose genome has been augmented" the depend claims merely require that their subject matter be derived therefrom. Since the dependent subject matter involves generation via a sexual cycle and maize was known in the art to undergo meiosis in which allelic segregation is manifested in progeny, or in the case of claim 2 in which chimeric division is possible, and there is no procedure or limitation in the independent claim to ensure that the subject matter therein is not chimeric, the $R_0$ plants, seeds and progeny encompass the same in which due, to the above observation, would include chimeric material or that which failed by fate not to receive the non-native DNA of interest. Such material would read on $R_0$ plants, cells, seeds and progeny derived from transgenic plant in which the DNA of interest was not present. These would be identical to plant found in nature and are thus non-patentable. Since this material would be without expression, it is not clear what new property, trait, characteristic or utility the products as claimed would possess which would distinguish them from naturally occurring products. See American Wood v. Fiber Disintegrating Co., 90 U.S. 556 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 USPQ 193 (1980).

Claims 44-46 are provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 33-35 of copending application Serial No. 07/636089. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 1-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-68 of copending application serial no. 07/508045. Although the conflicting claims are not identical, they are not patentably distinct from each other because each application is drawn to fertile transgenic maize in which the genome is augmented by the addition of DNA not normally found in maize or if found in maize is inserted, modified, altered or otherwise manipulated to the extent that it affords a change that is detectable over maize not transformed by phenotypic or genotypic

change. Each application differs by the specific recitation of the DNA of interest which is deemed to be experimenter choice.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Claims 11, 14, 15, 29, 47, 60, and 63-67are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Markush group presented in the above claim are improper in the recitation of the limitation of "comprises" or 'comprising" instead of "consisting of." (See *Ex Parte Dotter*, 12 USPQ 300 (CCPA 1980) and MPEP § 706.03 (y)). .

Claim 43 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "non-maize DNA" is both vague and indefinite. To the person having ordinary skill in the art DNA is DNA. If it is Applicants' intention to limit the subject matter to DNA derived from an organism that is art recognized to not be member of the plant kingdom it is suggested that the claim be reworded to indicate the same. If it is Applicants' intention to limit the material to DNA codons which are not optimized for expression in plant, and thus may be considered --by sequence frequency alone -- of non-plant origin, that should be claimed. However, as claimed it remains indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention

Claims 47 and 57 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "not normally expressed" is both vague and indefinite. A person having ordinary skill in the art could read this limitation to include DNA modification for codon usage or to DNA sequences not found in what is art recognized as maize. Accordingly the claimed subjected matter is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description and enabling disclosure for the claimed invention

The specification teaches the production of maize plants in which the GUS, bar, lux, hyg, aroA, $R_1C_1$ Bt, Adh, pinII dapA, zein Z10 and mtlD gene constructs have been inserted in transgenic $R_0$ plant and progeny. Expression is evidence in $R_0$ plants for all but Adh, pinII, dapA, Z10 and mtlD (Table at page 204-205) and in $R_1$ progeny except for aroA, R1C1, adh, pinII, dapA, Z10 and mtlD and as such does not evidence what phenotype the $R_0$ plant or progeny would have. The specification does not teach what characteristics, traits or utility the insertion of any other DNA construction in which expression of the DNA of interest is demonstrated or alternatively the inactivation or modification of the expression of a "native" gene is afforded. As such the insertion of any "transposable element" "exogenous" gene , "selectable or screenable" marker, or native gene (such as the α-amylase for example), a MAR region, or a herbicide, insect, fungal resistance gene or jellyfish gene, or a promoter and 3' region are operably linked to the same generic and specific lectins, structural proteins such as hevein gene, chitenase gene, avermectin, aequorin, CPTI and other protease inhibitors, estrases, nitrilase genes, would, in the absence of expression, not be considered as adequately enabled or described to one of ordinary skill in the art as mandated by compliance with § 112, first paragraph

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person."

Claims 1-67 are provisionally rejected, ~~and claims 49, 69-70, 72, 74, 77-81, remain provisionally rejected;~~ under 35 U.S.C. § 103, based on 35 U.S.C. § 102(e) as being obvious over copending application serial number 07/508045.

The claims noted above are drawn to maize plants that are further limited by the process term "transgenic " in which independent claim 1 further limits the subject matter to a maize plant whose DNA is augmented relative to that of the corresponding nontransgenic plant preparable by method steps of contacting cells and a DNA preparation including the step of microprojectile bombardment in which fertile transgenic plants that contain the DNA are identified. The claimed subject matter does not evidence the expression of the broadly claimed DNA in that no demonstration of how a transgenic plant comprising transposable elementary, exogenous gene encoding a selected trait, "α-amylase", a MAR region, herbicide, insect, fungal resistant for example, would differ from those found in nature. As no demonstration of the expression or the effects of "genetic component" on the expression of can be found in the claimed plants, seeds, or progeny it remains unclear what new property, trait, characteristic, or utility the products claimed would possess which would distinguish them from naturally non-occurring products. The plants as claimed, in the absence of a demonstration of the new trait etc., have the same characteristics and utility as those found in nature. These plants and to the extent that "transgenic" may be read as a process limitation do not constitute patentable subject matter. See American Wood v. Fiber Disintegrating Co., 90 U.S. 556 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 USPQ 193 (1980).

Claims 1-, 2, 5, 9-16, 43-46 and 61 are rejected under 35 U.S.C § 103 as being clearly anticipated by Spencer et al. in view of Phillips et al.

Spencer et al. (FASEB Poster) disclose the regeneration of a A188xB73 maize plant which evidences the transformation and expression of a transgenic bar gene in maize. Spencer et al. do not teach the retention of fertile plants, however, the same are considered manifest as the plant cell line employed in the process of biolistic transformation was an embryogenic suspension cell culture and the same were art recognized as totipotent. Thus in the absence of evidence to the contrary the inherent fertility of the cell line is assumed. If, however, the cell line of Spencer et al. were not fertile the selection of fertile plants from a maize type II cell culture was well known as evidenced by Phillips. Phillips et al. (pages 345-387, see section 5-2.8) discloses that the regeneration of maize plants from cell/tissue culture routinely produces fertile plants.

Accordingly, the modification of the method of Spencer et al. by the retention of fertile plants, as suggested by Phillips et al. was well within the ordinary skill of the art at the time the claimed invention was made. Thus, the claimed invention as a whole was clearly *prima facie* obvious in view of the references, in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 1-67 are rejected under 35 U.S.C. 103 as obvious over Goldman et al. in view of Applicants acknowledged state of the prior art

Goldman et al. (entire patent, especially column 15) teach the obtention of fertile transgenic maize plants in which the genome of said plants have been augmented by the heritable insertion of exogenous DNA from a transformation process. The plants produced enzymatic activity of lysopine including both mobilization and transfer functions. The fertile nature of the plants is evidenced by the heritable transfer of non-native enzymatic activity via pollination from the $R_0$ plant to seedlings of said plant (progeny) which displayed transgenic augmented maize genome. Goldman et al. do not teach the obtention of maize plant in which the have their genomes augmented by GUS, bar, lux, hyg, aroA, $R_1C_1$ Bt, Adh, pinII dapA, zein Z10 and mtlD. The person having ordinary skill in the art would view these genes and their insertion and expression in a transgenic host to be dependent on the availability of the DNA coding sequence to those of ordinary skill in the art. Each limitation set forth above, in terms of

the genes of interest, were available in the prior art. This was acknowledged by Applicants at page 107-112 of the specification which evidenced the availability of gene and DNA construction to a person having ordinary skill in the art in the art. For example, the *bar* gene, useful as a herbicide resistance gene (PPT resistance)is evidenced at page 129 of the specification. The 5-enol-pyruvyl-3-phosphoskimate synthetase (EPSP gene) is acknowledged at pages 122 as known to the art for use in producing transformed glyphosate resistant plants. Insect resistant genes (BT) and genes that modify storage protein content (zein) are taught as known to the art beginning at pages 131 and 219, respectively. In each specific recitation of a gene or gene element the concept to use the same in transformation was either demonstrated or suggested. Thus a person having ordinary skill in the art would view the use of prior art elements as the optimization of process parameter and the selection of one elements, in the absence of unexpected results, to be obvious. Accordingly, the modification of Goldman et al. by the use of prior art genes or gene elements was well within the ordinary skill of the art at the time the claimed invention was made. Thus, the claimed invention as a whole was clearly *prima facie* obvious in view of the references, in the absence of sufficient, clear, and convincing evidence to the contrary.

Claim 7, newly added, are rejected under 35 U.S.C § 103 as being unpatentable over Robertson.

Robertson (page 10) disclose the transfer and effects of the same of the transposable element Mu via backcross breeding into maize inbred lines B73, Mo17, A632 and B76. Robertson does not teach the plant to comprise the limitation of being "transgenic," however, the same is view as a process limitation that does not serve to distinguish plants produced by any other process that possess the same combination of prior art elements. Furthermore, the definition of transgenic (page 28) merely limits the material to that into which new DNA sequences are integrated. Thus as the process of Robertson (backcrossing) leads to the integration of the Mu transposable element and its expression or effect of the maize genome is clearly taught the teachings of Robertson are viewed as making the claimed invention *prima facie* obvious in the absence of evidence to the contrary.

Claim 20, is rejected under 35 U.S.C § 103 as being unpatentable over Coe et al.

Coe et al. (page 138) disclose the activity of the R allele in maize to affect plant anthocyanins and related pigments. Coe et al. do not teach the plants to comprise limitation of being "transgenic" however, the same is view as a process limitation that does not serve to distinguish plants produced by any other process that possess the same combination of prior art elements. Furthermore, the definition of transgenic (page 28) merely limits the material to that into which new DNA sequences are integrated. As the R alleles of maize and their effects on the maize genome have been well known the teachings of Coe et al. are viewed as making the claimed invention *prima facie* obvious in the absence of evidence to the contrary.

7/2/94

Claim 25, newly added, is rejected under 35 U.S.C § 103 as being unpatentable over Levitt in view of Sass.

Levitt (page 241) teaches that α-amylase activity resides in the aleurone layer and when stimulated during germination leads to the conversion of starch in the endosperm to sugar. Levitt does not teach the presence of the aleurone layer in maize, however, the same was a well known component of all monocots, such as maize, and constitute the tissue in which α-amylase activity resides. In this regard Sass (page 98) is cited to demonstrate the presence of the aleurone in maize. Neither reference teaches a maize plant containing the α-amylase gene in which the plant possess the further limitation of transgenic, however, as maize plants in the prior art possess the α-amylase gene in its native state and no further limitation in terms of expression or physiological effect is claimed the teachings cited above are view as making the claimed invention *prima facie* obvious in the absence of evidence to the contrary.

Claims 1-4 and 9 are rejected under 35 U.S.C § 103 as being unpatentable over Poehlman.

Poehlman (page 452) teach the natural hybridization between maize (*Zea mays*) and diploid teosinte (*Zea diploperennis*). These hybrid comprise plants that have DNA that is novel, in comparison to maize DNA and not of maize origin. Poehlman does not teach the plants to comprise the limitation of being transgenic produced by a process including microprojectile bombardment to augment the maize genome, however, the maize genome is augmented by the incorporation of teosinte DNA by conventional hybridization. The limitations of being transgenic and the process including microprojectile bombardment are simply process limitations that in the

absence of traits or characteristics not found in the prior art do not serve to distinguish the product produced by any other process. Accordingly the claimed invention is clearly *prima facie* obvious in the absence of evidence to the contrary.

No claim is allowed.

Any inquiry concerning this or earlier communication from the examiner should be directed to Gary Benzion, Ph.D whose telephone number is (703) 308-1119. The examiner can normally be reached on Monday-Friday from 8 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Elizabeth C. Weimar can be reach on (703-308-0254).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703)-305-3014.

Benzion
06/27/94

GARY BENZION
PRIMARY EXAMINER
GROUP 1800